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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/599,020   | 09/18/2006  | Frederic Ben         | 58767.000017        | 3183             |
| 21967 7590 04/06/2012<br>HUNTON & WILLIAMS LLP<br>INTELLECTUAL PROPERTY DEPARTMENT<br>2200 Pennsylvania Avenue, N.W.<br>WASHINGTON, DC 20037 |             |                      |                     |                  |
| EXAMINER   |             |                      |                     |                  |
| LSTVOYB, GREGORY   |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1765   |             |                      |                     |                  |
| MAIL DATE  |             | DELIVERY MODE        |                     |                  |
| 04/06/2012   |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/599,020

**Applicant(s)**

BEN ET AL.

**Examiner**

GREGORY LISTVOYB

**Art Unit**

1765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 January 2012.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on \_\_\_\_; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 5) ☒ Claim(s) 16, 18-32, 34 and 35 is/are pending in the application.
- 5a) Of the above claim(s) 28-32 is/are withdrawn from consideration.
- 6) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 7) ☒ Claim(s) 16, 18-27, 34 and 35 is/are rejected.
- 8) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 9) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-889)  
Paper No(s) Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s) Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

**DETAILED ACTION**

The previous prior art rejection under Gruber et al (US 6355772) in view of Bowman (US 3047524) as evidences by Nevin et al (US 4273920) maintained and therefore it is proper to make this rejection FINAL

***Claim Rejections - 35 USC § 112***

The amendment to the claims renders the previous rejection moot.

***Claim Rejections - 35 USC § 103***

Claims 16, 18-27 and 34 rejected under 35 U.S.C. 103(a) as being unpatentable over Gruber et al (US 6355772) in view of Bowman (US 3047524) as evidences by Nevin et al (US 4273920) (all cited in the previous Office Action)

Regarding new claim 35, Gruber discloses polydispersity index of 1.34 (see Example 8). All other limitations recited in rejected claim 16.

The rejection can be found in the NON-FINAL office action mailed 1/3/2011 and is herein incorporated by reference.

***Response to Arguments***

Applicant's arguments filed 1/9/2012 have been fully considered but they are not persuasive.

Applicant submits that Methanol used by Gruber( the primary reference) in Example 8 is not a part of a catalytic system.

However, both Gruber and Applicant teaches an alcohol as a part of reaction mixture (see Gruber: Column 15, line 5 and Applicant: Specification, Examples 5-8), which used for molecular weight control. Monohydric alcohol (i.e. n-Pentanol or Methanol) has only one functional group and thus can be located only in the chain end of the resulting polymer chain. Gruber clearly teaches alcohol a molecular weight control agent (see Column 15, line 5) meaning that the reagent locates at the terminal position of the resulting polymer chain.

Applicant argues that Bowman discloses glycolic acid and alcohol as separate components used in polymerization for stabilization of polymer characteristics.

However, it is clear that Bowman uses aliphatic alcohol as a molecular weight regulator (the same function as in Applicant and Gruber's disclosures).In particular, alcohol added to the reaction mixture immediately after the desired melting point is achieved in order to stabilize the polymer properties. It means that the reagent is added to prevent further polymerization to occur (i.e. stabilizing its molecular weight) by deactivating the polymer ends.

Again, Bowman's reference applies in the Rejection exclusively in order to specify alcohol amount and structure.

Applicant further submits that Bowman does not mention the use of any catalytic system and thus its combination with Gruber is improper.

Examiner disagrees. In both Gruber and Bowman's disclosures alcohol applies to stabilize molecular weight of the polylactic/polyglycolic acid polymer. In both cases alcohol does not play a role of catalyst, but rather molecular weight regulator.

Applicant submits that his polymerization is very different from the one of Gruber, Bowman and Nevin. In particular, Applicant states that in his process lactide undergo ring opening polymerization (ROP).

This is incorrect. Gruber discloses a polymerization of L-Lactide (see Example 8). This material (not lactic acid) has a cyclic structure and thus polymerized via ROP mechanism.

Thus, Gruber (primary reference) discloses the same polymerization process as it claimed in the Application examined.

Bowman and Nevin references added to clarify type and amount of molecular weight controlling agent, which is applicable for both direct polymerization of lactic acid and ROP process for lactide.

Finally, Applicant states that use of co-oligomerization additive leads to high percent of conversion (greater than 95%), while Gruber can achieve only 79.5% with his polymerization system.

However, Gruber achieves such a high conversion (greater than 95%) in majority of his Control samples (see Table 18).

Example 8, there Amberlist 36 is used as a catalyst is not representative enough for making conclusion about monomer conversion, because only one experimental data point is disclosed. Ratio between lactide and catalyst, reaction temperature and time are not varied. In other words, the catalytic system presented is not optimized. Therefore, direct comparison between Gruber's Example 8 and Applicant's catalytic system is not valid due to lack of experimental data.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GREGORY LISTVOYB whose telephone number is (571)272-6105. The examiner can normally be reached on 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GL  
/GREGORY LISTVOYB/  
Examiner, Art Unit 1765

Application/Control Number: 10/599,020  
Art Unit: 1765

Page 7